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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,072	04/13/2001	David R. Goodlett	P-IS 4584	3882

23961 7590 07/26/2002

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EXAMINER
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GALITSKY, NIKOLAI M

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09 835,072

Examiner

Nikolai M. Galitsky

Applicant(s)

GOODLETT ET AL.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a) in no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply, within the statutory minimum of thirty (30) days, will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply, and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may, reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other \_\_\_\_

### **DETAILED ACTION**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to a method of determining an amino acid sequence of polypeptide by constructing a graph from mass spectra, classified in class 702, subclass 27. If this group is elected, then the below summarized specie election also is required.
- II. Claims 19-29, drawn to a method of determining an amino acid sequence of polypeptide by differentially labeling two or more polypeptide mixtures, classified in class 702, subclass 27. If this group is elected, then the below summarized specie election also is required.
- III. Claims 30-39, drawn to a method of determining an amino acid sequence of a parent polypeptide from mass spectra of two or more differentially labeled polypeptide fragments of parent polypeptide by assigning a mass and weighting characteristic, classified in class 702, subclass 27. If this group is elected, then the below summarized specie election also is required.

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- IV. Claims 40-55, drawn to a method of determining an amino acid sequence of a parent polypeptide from mass spectra of two or more differentially labeled polypeptide fragments of parent polypeptide by identifying a paired signal from mass spectra, classified in class 702, subclass 27. If this group is elected, then the below summarized specie election also is required.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I --IV are drawn to the methods of determining an amino acid sequence of polypeptide using mass spectra. Each of the above invention Groups are directed to mass spectra practice with a different set of requirements in the determination an amino acid sequence of polypeptide as summarized above and in the below table.

Group	constructing a graph	polypeptide mixtures	assigning a mass	identifying a paired signal	orienting amino acid names
I	Yes	No	No	No	No
II	Yes	Yes	No	No	No
III	No	No	Yes	No	Yes
IV	No	No	No	Yes	Yes

Each of the above Groups are directed to different and distinct methods of constructing a graph, polypeptide mixture, assigning a mass, identifying a mass, identifying a paired signal, and orienting amino acid names and require thus distinct and different searches for each such set of elements. Therefore, there clearly would be an undue search burden to search all Groups

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together as each search would be directed to different methods of determining amino acid by mass spectrometry thus supporting this restriction requirement as given above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

#### SPECIE ELECTION REQUIREMENT FOR GROUPS I-IV:

This application contains claim directed to the following patentably distinct species of the claimed invention: These species are distinct because they each add a feature to the mass spectra methods with different and distinct functions which each would require a separate and burdensome search to add to the search for the basic determination amino acid sequence of polypeptide as defined above.

Groups I-IV:

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Specie A: internal amino acid residue;

Specie B: terminal amino acid residue;

Specie C: terminal and an internal amino acid residue.

Needed if Group I or Group II is elected:

Specie D: an amino acids post-translational modification;

Specie E: an amino acids without modifications.

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicants are advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, the specie elections for examination purposes as indicated is proper.

Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR § 1.143).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai Galitsky, Ph.D., whose telephone number is (703) 308-2422. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

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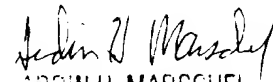
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 24, 2002

NMG

  
ARDIN H. MARSCHEL  
CHIEF, PATENT EXAMINER